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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,387	11/29/2005	Dan Pitulia	43318-225722	5702

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VENABLE LLP  
P.O. BOX 34385  
WASHINGTON, DC 20043-9998

EXAMINER
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PENDLETON, DIONNE

ART UNIT	PAPER NUMBER
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2615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/558,387

Applicant(s)

PITULIA, DAN

Examiner

Dionne H. Pendleton

Art Unit

2615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) n/a is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 1,3 and 6** are rejected under 35 U.S.C. 102(b) as being anticipated by **Hakansson (US Patent No. 5,735,790)**.

#### **Regarding claim 1,**

Hakansson teaches an implant device for bone anchored hearing aids comprising a screw-shaped anchoring element fixture **2** for anchorage in the bone tissue; an abutment sleeve **7** for skin penetration and connected to the fixture **2** by means of a screw connection **6** thereby forming a pre-mounted unit, and a tool (*inherently required*) for installing the implant into the bone which is arranged to cooperate with a tool engaging portion of the abutment sleeve **10a,10,11**.

#### **Regarding claim 3,**

Hakansson teaches that the abutment sleeve is provided with a tool engaging portion **10a,10,11**, shown in **Figure 1** as being provided with an annular seat (recess) **9** , as well as a bead **11** which cooperates with the wall **7** of the coupling part to provide an additional recessed portion **13** for engaging with an tool member.

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**Regarding claim 6,**

Hakansson teaches a tool for engaging with a screw-shaped anchoring element fixture **2**, wherein the tool comprises ring **17a**, made to be resilient (**see column 3, lines 41-44**) for cooperation with the edge of the abutment sleeve.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 2,4,5,7 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hakansson (US Patent No. 5,735,790)**.

**Regarding claim 2,**

Hakansson teaches the invention of claim 1. Hakansson does not clearly teach that the fixture is self-tapping. However, the Examiner takes *Official Notice* that it is well known in the art and would have been obvious to employ self-tapping slits on the insertion end of an article for implantation, thereby obviating the need for additional hole cutting tools. (*See Pertinent Reference(s) Cited Below.*)

**Regarding claims 4-5,**

Hakansson inherently teaches a tool, necessary for positioning the disclosed hearing aid device within the skull of a person. Hakansson does not clearly teach a tool as specifically constructed, including a first part for installing the implant via machine driver, and a second part for manual insertion of the implant device. However, the Examiner takes *Official Notice* that special driver tools for manual insertion of an implant device are well known in the art and would have been obvious for the purpose of screwing a portion of the implant device into the bony tissue of patients. *(See Pertinent Reference(s) Cited Below.)*

**Regarding claims 7 and 8,**

Hakansson teaches the invention of claim 6. Hakansson does not clearly teach that the implant device is delivered in sterile packaging as claimed. However, the Examiner takes *Official Notice* that it is well known in the art and would be obvious to use any reasonable commercially available sterile packaging for surgical articles, thereby avoiding contamination of the surgical article and maintaining the highest degree of cleanliness. *(See Pertinent Reference(s) Cited Below.)*

***Conclusion***

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

**Carlsson US 6,053,90** teaches self tapping holder.

**West US 5,987,344** teaches a manual driver.

**Kuzma US 6,628,991** teaches a manual driver.

**Behl US 6,802,839** teaches sterile packaging.


**Branemark US 4,712,681** teaches sterile titanium packaging.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne H. Pendleton whose telephone number is 571-272-7497. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sinh Tran can be reached on 571-272-7564. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
D. Pendleton

  
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